REMARKS

I. The Office Action

The Office maintained the restriction requirement and acknowledged Applicant's election of Group I (claims 1-17). The Office withdrew the species election requirement. Claims 1-17 are pending and currently under examination.

The Office acknowledged consideration of the Information Disclosure Statement filed July 19, 2007. The Office objected to claim 1 for allegedly containing improper syntax. The objection is moot in view of the amendment to claim 1.

Claims 1-8 were rejected under 35 U.S.C. § 102(b) for assertedly being anticipated by International Patent Publication WO 00/23097 ("Rudling et al."). Claims 9-16 were rejected under 35 U.S.C. § 103(a) for assertedly being obvious in view of Rudling et al. taken with Carr, *AIDS*, *17*, S141-148 (2003) ("Carr") (claims 9-14) and Van Gaal and Leeuw, *Diabetologia*, *46*, M44-M50 (2003) ("Van Gaal and Leeuw") (claims 14-16). Claim 17 was rejected under 35 U.S.C. § 103(a) for assertedly being obvious in view of Rudling et al. taken with Oral et al., *N. Engl. J. Med.*, *346*, 570-578 (2002) ("Oral et al."). Reconsideration of these rejections is hereby requested.

II. Amendments to the Specification and Claims

Claims 1 and 8-10 have been amended to recite "lipodystrophy," as supported by the instant specification at, e.g., page 6, line 9, through page 7, line 33; and at page 9, lines 24-26 (all references to the instant specification refer to WO 2005/074916). Claims 2, 3, 6, and 7 were amended to unify the language used throughout the claims without altering the claim scope. Claims 12, 14, and 15 were amended to correct grammatical errors and, with respect to claim 15, provide the terms corresponding to listed acronyms. Claims 18-24 have been cancelled for being directed to a non-elected invention. Applicants reserve the right to pursue the subject matter of claims 18-24 in a divisional or continuation application. No new matter has been added by way of these amendments.

III. Discussion of Rejection under 35 U.S.C. § 102(b)

Claims 1-8 were rejected under Section 102(b) for assertedly being anticipated by Rudling et al. On the contrary, the disclosure of Rudling et al. does not anticipate the pending claims. The claims, as amended, are directed to a method of treating lipodystrophy. In contrast, Rudling et al. discloses a method of treating *familial hypercholesterolemia*. Lipodystrophy, as recited in the pending claims, is *not* a form of hypercholesterolemia, however. Hypercholesterolemia is marked by elevated levels of total cholesterol in circulation. *See, e.g., Harrison's Principles of Internal Medicine* 2249 (Braunwald et al. eds., 15th ed., McGraw-Hill 2001) (submitted herewith). It is a metabolic abnormality associated with disordered lipid and/or glucose metabolism, as noted in the instant specification at, for example, page 8, lines 1-13. Lipodystrophy, on the other hand, is a syndrome caused by a deficiency and/or destruction of adipocytes and characterized by an abnormal distribution of adipose tissue, i.e., abnormal quantities of adipose tissue in various regions of the body. Instant specification, page 1, lines 11-14; Lichtenstein et al., *AIDS*, *15*, 1389-1398 (2001) (submitted herewith) (designating patients displaying fat maldistribution as suffering from lipodystrophy); *Harrison's Principles of Internal Medicine* at 2316 (submitted herewith). Lipodystrophy may be *associated* with metabolic disturbances such as hypertriglyceridemia, hyperlipidemia, hepatic steatosis, and severe insulin resistance. *See* specification, page 8, lines 1-13. However, hypercholesterolemia is simply not the same disorder as lipodystrophy. This point is underscored by Rakatoambinina et al., *JAIDS*, *27*(5), 443-449 (2001) (submitted herewith), which notes that a relatively high level of lipodystrophy patients observed in the reported study exhibited triglyceride and cholesterol values within normal limits. Rudling et al. does not teach a method of treating lipodystrophy. Indeed, there is nothing in the cited reference that would suggest that hypercholesterolemia therapies would also be useful in treating lipodystrophy. Accordingly, the reference does not anticipate the pending claims, and the rejection under Section 102(b) should be withdrawn.

IV. Discussion of Rejection under 35 U.S.C. § 103(a)

The Office rejected claims 9-17 under Section 103(a) for assertedly being obvious over Rudling et al. in view of either Carr alone, Carr and Van Gaal and Leeuw, or Oral et al. This rejection is respectfully traversed for the reasons set forth below.

A. Claims 9-16 are patentable over the cited art.

The Office contends that the subject matter of claims 9-14 is unpatentable for assertedly being obvious under Section 103(a) over the disclosure of Rudling et al. taken with the disclosure of Carr. The Office acknowledges that Rudling et al. does not disclose a method of treating an "HIV-related dystrophy abnormal lipid distribution disorder," but asserts that Carr discloses (1) using growth hormone to reduce intra-abdominal adiposity and buffalo humps, (2) using atorvastatin or pravastatin for treating high cholesterol or HDL, and (3) using metformin to improve insulin sensitivity. According to the Office, it would be obvious to administer the combination treatment of Rudling et al. to an HIV patient to treat an abnormal lipid distribution disorder because HIV patients comprise high plasma cholesterol, high LDL, or low HDL, as assertedly taught by Carr.

Pending claims 9 and 10 are directed to a method of treating HIV-related lipodystrophy comprising administering to a subject a growth hormone and a statin-based therapeutic agent. For the reasons above, Rudling et al. does not teach administering growth hormone and a statin-based therapeutic agent to treat lipodystrophy. Carr does not cure the deficiencies of Rudling et al. in this respect. Like Rudling et al., atorvastatin and pravastatin are mentioned in Carr *only* in the context of lowering lipids. Carr does not teach or suggest administering atorvastatin or pravastatin to treat *lipodystrophy* (a clinical disorder distinct from hyperlipidemia), much less administering *both* growth hormone and a statin-based therapeutic to treat lipodystrophy. Indeed, there is no express teaching in Carr to administer *any* of the listed treatments together. Furthermore, the Office failed to establish that one of ordinary skill would have had a reasonable expectation of success in treating lipodystrophy using growth hormone and a statin-based therapeutic. As noted above, hypercholesterolemia (hyperlipidemia) and lipodystrophy are different clinical disorders. The cited references are silent with respect to the effect of statin-based therapeutic agents on lipodystrophy, and the Office provided no scientific rationale regarding the predictability of treating lipodystrophy based on a treatment for hypercholesterolemia. Accordingly, the rejection of claims 9 and 10 under Section 103(a) cannot stand.

In considering the rejection of claims 11-13 as obvious, it is noted that Carr's disclosure of diabetes incidence in HIV-infected patients does not cure the deficiencies

described above. Regarding claim 14, the reference suggests using metformin to improve insulin sensitivity; however, metformin is not an insulin secretagogue. *See, e.g.*, Monami et al., *Diabetes Metab. Res. Rev.*, *22*(6), 477-82 (2006) (submitted herewith). Carr does not teach or suggest using an insulin secretagogue in combination with growth hormone and a statin-based therapeutic to treat lipodystrophy, and cannot be considered as rendering obvious the subject matter of claim 14, alone or in combination with Rudling et al.

The Office rejected claims 14-16 for assertedly being obvious in view of Rudling et al. taken in view of Carr and Van Gaal and Leeuw. According to the Office, Van Gaal and Leeuw teaches a combination therapy for type-2 diabetes employing non-glucose-dependent insulin secretagogues. However, Van Gaal and Leeuw does not cure the deficiencies of Rudling et al. and Carr described above by merely disclosing a potential treatment for diabetes, a metabolism disorder that is *not* a lipid distribution disorder (i.e., lipodystrophy). The combination of Rudling et al., Carr, and Van Gaal and Leeuw does not teach or suggest a method of treating lipodystrophy using a growth hormone and a statin-based therapeutic agent, as required by claims 14-16.

For the reasons set forth above, the subject matter of claims 9-16 are patentable over the cited art. Applicants respectfully request withdrawal of the rejection under Section 103(a).

B. Claim 17 is patentable over the cited art.

The Office rejected claim 17 for assertedly being obvious under Section 103(a) over Rudling et al. taken in view of Oral et al. Claim 17 is directed to a method of treating lipodystrophy comprising administering to a subject a growth hormone, a statin-based therapeutic agent, and leptin. The combination of Rudling et al. and Oral et al. fails to render the claimed subject matter obvious. For the reasons stated above, Rudling et al. does not teach or suggest administering a growth hormone and a statin-based therapeutic agent for the treatment of lipodystrophy; instead, the reference describes a method of treating hypercholesterolemia, a different clinical disorder. Oral et al. does not cure the deficiencies in the disclosure of Rudling et al. because Oral et al. does not disclose or suggest treating any disorder with either a growth hormone or a statin-based therapeutic agent. Consistent with this position, the Office has not provided a reason for combining Rudling et al. and Oral et

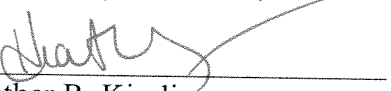
al., and has not established a reasonable expectation of success in combining the references. The references, alone or in combination, fail to disclose or suggest using growth hormone, a statin-based therapeutic agent, and leptin to treat lipodystrophy. Accordingly, the subject matter of claim 17 is patentable over the cited art, and the Section 103(a) rejection should be withdrawn.

V. Conclusion

In view of the foregoing amendments and remarks, Applicant believes the pending application is in condition for allowance, and the examiner is respectfully requested to pass this application to issue. If, in the opinion of the examiner, a telephone conference would expedite prosecution of the application, the examiner is invited to contact the attorney listed below.

Dated: June 30, 2008

Respectfully submitted,

By 

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